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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09 664,519 | 09 18 2000 | Michael C. Barney | 660005.98757 | 4670 |

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EXAMINER

KAM, CHIH MIN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1653

DATE MAILED: 12/10/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/664,519

Applicant(s)

BARNEY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 12-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 12-14 is/are rejected.
- 7) ☒ Claim(s) 8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Status of the Claims

1. Claims 1-8 and 12-14 are pending.

Applicants' amendment filed on September 26, 2002 (Paper No. 9) is acknowledged and Applicants' response has been fully considered. Claims 1 and 12 have been amended, and claims 9-11 have been cancelled. Thus, claims 1-8 and 12-14 are examined.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

2. The previous rejection of claims 1-14, under 35 U.S.C. 112, second paragraph, regarding the term "mixtures thereof, and combinations thereof" or "from about 0.2 ppm to about 25 ppm", is withdrawn in view of applicants' cancellation of the claim, applicants' amendment to the claim, and applicants' response at pages 3-4 in Paper No. 9.

Claim Rejections - 35 USC § 102 & 103

3. The previous rejection of claims 9-11 under 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Nutter *et al.* (WO 98/11883), is withdrawn in view of applicants' cancellation of the claim in Paper No. 9.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1, 2, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nutter *et al.* (WO 98/11883) in view of Todd *et al.* (U. S. Patent 5,082,975).

Nutter *et al.* teach a method of killing cancer cells or bacterial cells, and/or inhibiting their growth through the use of beta acids (also known as lupulones) such as hexahydrocolupulone (HHC) (page 4, line 12-page 5, line 10), and a pharmaceutical composition comprising the beta acid and a pharmaceutical carrier (page 9, lines 14-22; claim 6), which can be used as a topical ointment (page 9, lines 23-25; claim 7) to inhibit the growth of *Staphylococcus Aureus* (page 6, line 27-page 7, line 6). The reference indicates lupulones can be administered to achieve the plasma concentration from 0.5 to 75 μM (page 12, lines 4-6; about 0.2 - 62.5 $\mu\text{g/l}$ using MW 395 of HHC), which corresponds to 0.2 - 62.5 ppm. However, the reference does not indicate HHC at 0.2-25 ppm would not prevent the growth of lactobacilli. Todd *et al.* (U. S. Patent 5,082,975) shows HHC at high concentration (50-200 ppm, column 7, lines 54-58) inhibits the growth of certain lactobacilli. Therefore, if the concentration of HHC is reduced to a lower concentration such as in the range of 0.2-25 ppm, the inhibition of the growth of lactobacilli would be lessened, thus allow the growth of lactobacilli (claims 1, 2). At the time of invention was made, it would have been obvious to one of ordinary skill in the art that HHC at lower concentration such as 0.2-25 ppm would inhibit the growth of *S. aureus* without preventing the growth of lactobacilli as indicated by Nutter *et al.* and Todd *et al.* Thus, the combined references result in the claimed invention and was, as a whole, *prima facie* obvious at the time the claimed invention was made.

Insofar as applicant's response at page 3 of the response filed 26 September 2002, applicant has cancelled claims 9-11 on the rejection of the claims being anticipated by or being

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obvious over Nutter *et al.* The current rejection is based on 35 U. S. C. 103(a) because Nutter *et al.* teach HHC at concentrations of 0.2 - 62.5 ppm inhibits the growth of Staphylococcus Aureus, and Todd *et al.* teach HHC at high concentrations (50-200 ppm) inhibits the growth of lactobacilli, thus, the inhibition of the growth of lactobacilli would be lessened when the concentration of HHC is reduced. In view of the teachings of Nutter *et al.* and Todd *et al.*, it would have been obvious that the combined references teach HHC at low concentrations such as 0.2-25 ppm inhibits the growth of S. aureus without preventing the growth of lactobacilli.

5. Claims 3-5 and 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nutter *et al.* (WO 98/11883) in view of Todd *et al.* (U. S. Patent 5,082,975) as applied to claim 1 above, further in view of Lefren *et al.* (U. S. Patent 4,431,427).

Nutter *et al.* teach a method of killing cancer cells or bacterial cells, and/or inhibiting their growth through the use of beta acids (also known as lupulones) such as hexahydrocolupulone (HHC) (page 4, line 12-page 5, line 10), and lupulones can be administered to achieve the plasma concentration from 0.5 to 75 μ M (page 12, lines 4-6; about 0.2 - 62.5 μ g/l using MW 395 of HHC), which corresponds to 0.2 - 62.5 ppm. Todd *et al.* (U. S. Patent 5,082,975) shows HHC at high concentration (50-200 ppm, column 7, lines 54-58) inhibits the growth of certain lactobacilli. The combined references teach HHC at a low concentration such as in the range of 0.2-25 ppm would inhibit the growth of lactobacilli without prevent the growth of lactobacilli (claim 1). However, Nutter *et al.* and Todd *et al.* do not disclose the use of a product comprising an absorbent and HHC. Lefren *et al.* teach a tampon containing an organic acid in the absorbent material such as cotton fibers to create a hostile but safe environment during the use of tampon to inhibit the growth of pathogenic bacteria such as S.

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aureus (column 1). Therefore, at the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use a product such as tampon as taught by Lefren *et al.* but substituting the organic acid with HHC in the absorbent material at concentration of 0.2-25 ppm (claims 3-5 and 12-14) to inhibit *S. aureus* without preventing the growth of lactobacilli to maintain normal bacterial flora in a use environment to avoid the onset of other bacterial infections. Thus, the combined references result in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

6. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

December 6, 2002

Christopher S. F. Low
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